

IN THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Complete Listing of Claims:

1. (Currently Amended) A method of suspending, preventing or delaying onset of type 1 diabetes in a subject in need thereof, the method comprising administering to the subject a pharmaceutically acceptable composition comprising a soluble fusion protein, wherein the fusion protein comprises at least one immunoglobulin having a variable region ~~eomposed of at least one CDR comprising a CDR1, a CDR2, or a CDR3~~ region, the at least one immunoglobulin having at least one protein fragment or peptide inserted within the variable region; wherein (a) the protein fragment or peptide is selected from the group consisting of a protein fragment or peptide derived from INS, a protein fragment or peptide derived from GAD where said protein fragment or peptide derived from GAD comprises GAD1 or GAD2, a diabetogenic epitope, and a T cell receptor engaging determinant, ~~or fragments of the foregoing;~~ and (b) the composition is administered to the subject in one or more dosage administrations.
2. (Original) The method of claim 1, wherein the immunoglobulin is human or humanized.
3. (Previously presented) The method of claim 1, wherein the subject is a human subject that has undergone IAA seroconversion.
4. (Previously presented) The method of claim 1, wherein administration of the composition to the subject results in down regulation of an autoreactive T cell.
5. (Previously presented) The method of claim 1, wherein the at least one protein fragment or peptide is inserted within a CDR region of the at least one immunoglobulin.

6. (Cancelled)
7. (Previously presented) The method of claim 5, wherein administration of the composition to the subject results in substantially reduced activation of an autoreactive T cell specific for the at least one protein fragment or peptide.
8. (Withdrawn) The method of claim 1, wherein the at least one protein fragment or peptide is derived from INS.
9. (Withdrawn) The method of claim 8, wherein the INS comprises soluble INS β .
10. (Withdrawn) The method of claim 9, wherein the soluble INS β is capable of binding to at least one Fc receptor.
11. (Withdrawn) The method of claim 10, wherein the Fc receptor is a Fc γ receptor.
12. (Withdrawn) The method of claim 10, wherein the composition is capable of being endocytosed by antigen presenting cells.
13. (Currently amended) The method of claim 1, wherein the at least one protein fragment or peptide is derived from GAD65 and comprises GAD1 or GAD2.
14. (Cancelled)
15. (Previously presented) The method of claim 13, wherein the subject is GAD positive.
16. (Previously presented) The method of claim 1, wherein the subject has not developed hyperglycemia at initiation of the administering step.

17. (Previously presented) The method of claim 1, wherein the subject expresses a type 1 diabetes predisposition marker at initiation of the administering step.
18. (Previously presented) The method of claim 1, wherein upon administration of the composition to the subject, the subject undergoes a dose dependent suspension, prevention, or delay in onset of type 1 diabetes.
19. (Previously presented) The method of claim 1, wherein administration of a first dosage of the composition occurs before the subject has developed type-1 diabetes.
20. (Withdrawn) A composition for suppressing the onset of type 1 diabetes in a subject that has undergone IAA seroconversion, the composition comprises: a pharmaceutically acceptable composition comprising at least one immunoglobulin selected from the group consisting of INS, GAD, an insulin protein, a peptide derived from insulin, a diabetogenic epitope, and a T cell receptor engaging determinant.
21. (Withdrawn) The method of claim 20 wherein the fusion protein is in soluble form.
22. (Previously presented) The method of claim 2 wherein the immunoglobulin is selected from the group consisting of IgG1, IgG2, IgG2a, IgG2b, IgG3, IgG4, IgGA, IgA1, IgA2, IgGE, IgD, IgE, or IgM.
23. (Currently Amended) The method of claim 5 wherein the at least one protein fragment or peptide is inserted [in] within the CDR3 region of the immunoglobulin.
24. (Currently Amended) The method of claim 23 wherein the at least one protein fragment or peptide is inserted [in] within the CDR3 region of the immunoglobulin in place of a D segment.

25. (Currently amended) The method of claim 13 wherein the at least one protein fragment or peptide derived from GAD65 comprises consists of amino acid residues 524-543 of GAD65.

26. (Currently amended) The method of claim 13 wherein the at least one protein fragment or peptide derived from GAD65 comprises consists of amino acid residues 206-220 of GAD65.